



Periodic Review / Retain Regulation Agency Background Document

Agency name	Board of Health Professions, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC75-20
Regulation title	Regulations Governing Practitioner Self-Referral
Document preparation date	2/28/12

This form is used when the agency has done a periodic review of a regulation and plans to retain the regulation without change. This information is required pursuant to Executive Orders 14 (2010) and 58 (1999).

Legal basis

Please identify the state and/or federal legal authority for the regulation, including (1) the most relevant law and/or regulation, and (2) promulgating entity, i.e., agency, board, or person.

The legal basis for establishing the Practitioner Self-Referral Act is found in Chapter 24.1 of Title 54.1 of the Code of Virginia:

§ 54.1-2410. Definitions.

As used in this chapter or when referring to the Board of Health Professions regulatory authority therefor, unless the context requires a different meaning:

"Board" means the Board of Health Professions.

"Community" means a city or a county.

"Demonstrated need" means (i) there is no facility in the community providing similar services and (ii) alternative financing is not available for the facility, or (iii) such other conditions as may be established by Board regulation.

"Entity" means any person, partnership, firm, corporation, or other business, including assisted living facilities as defined in § 63.2-100, that delivers health services.

"Group practice" means two or more health care practitioners who are members of the same legally organized partnership, professional corporation, not-for-profit corporation, faculty practice or similar association in which (i) each member provides substantially the full range of services within his licensed or certified scope of practice at the same location as the other members through the use of the organization's office space, facilities, equipment, or personnel; (ii) payments for services received from a member are treated as receipts of the organization; and (iii) the overhead expenses and income from the practice are distributed according to methods previously determined by the members.

"Health services" means any procedures or services related to prevention, diagnosis, treatment, and care rendered by a health care worker, regardless of whether the worker is regulated by the Commonwealth.

"Immediate family member" means the individual's spouse, child, child's spouse, stepchild, stepchild's spouse, grandchild, grandchild's spouse, parent, stepparent, parent-in-law, or sibling.

"Investment interest" means the ownership or holding of an equity or debt security, including, but not limited to, shares of stock in a corporation, interests or units of a partnership, bonds, debentures, notes, or other equity or debt instruments, except investment interests in a hospital licensed pursuant to Article 1 (§ 32.1-123 et seq.) of Chapter 5 of Title 32.1.

"Investor" means an individual or entity directly or indirectly possessing a legal or beneficial ownership interest, including an investment interest.

"Office practice" means the facility or facilities at which a practitioner, on an ongoing basis, provides or supervises the provision of health services to consumers.

"Practitioner" means any individual certified or licensed by any of the health regulatory boards within the Department of Health Professions, except individuals regulated by the Board of Funeral Directors and Embalmers or the Board of Veterinary Medicine.

"Referral" means to send or direct a patient for health services to another health care practitioner or entity outside the referring practitioner's group practice or office practice or to establish a plan of care which requires the provision of any health services outside the referring practitioner's group practice or office practice.

§ 54.1-2411. Prohibited referrals and payments; exceptions.

A. Unless the practitioner directly provides health services within the entity and will be personally involved with the provision of care to the referred patient, or has been granted an exception by the Board or satisfies the provisions of subsections D or E of this section or of subsections D or E of § 54.1-2413, a practitioner shall not refer a patient for health services to

an entity outside the practitioner's office or group practice if the practitioner or any of the practitioner's immediate family members is an investor in such entity.

B. The Board may grant an exception to the prohibitions in this chapter, and may permit a practitioner to invest in and refer to an entity, regardless of whether the practitioner provides direct services within such entity, if there is a demonstrated need in the community for the entity and all of the following conditions are met:

- 1. Individuals other than practitioners are afforded a bona fide opportunity to invest in the entity on the same and equal terms as those offered to any referring practitioner;*
- 2. No investor-practitioner is required or encouraged to refer patients to the entity or otherwise generate business as a condition of becoming or remaining an investor;*
- 3. The services of the entity are marketed and furnished to practitioner-investors and other investors on the same and equal terms;*
- 4. The entity does not issue loans or guarantee any loans for practitioners who are in a position to refer patients to such entity;*
- 5. The income on the practitioner's investment is based on the practitioner's equity interest in the entity and is not tied to referral volumes; and*
- 6. The investment contract between the entity and the practitioner does not include any covenant or clause limiting or preventing the practitioner's investment in other entities.*

Unless the Board, the practitioner, or entity requests a hearing, the Board shall determine whether to grant or deny an exception within 90 days of the receipt of a written request from the practitioner or entity, stating the facts of the particular circumstances and certifying compliance with the conditions required by this subsection. The Board's decision shall be a final administrative decision and shall be subject to judicial review pursuant to the Administrative Process Act (§ 2.2-4000 et seq.).

C. When an exception is granted pursuant to subsection B:

- 1. The practitioner shall disclose his investment interest in the entity to the patient at the time of referral. If alternative entities are reasonably available, the practitioner shall provide the patient with a list of such alternative entities and shall inform the patient of the option to use an alternative entity. The practitioner shall also inform the patient that choosing another entity will not affect his treatment or care;*
- 2. Information on the practitioner's investment shall be provided if requested by any third party payor;*
- 3. The entity shall establish and utilize an internal utilization review program to ensure that practitioner-investors are engaging in appropriate and necessary utilization; and*

4. In the event of a conflict of interests between the practitioner's ownership interests and the best interests of any patient, the practitioner shall not make a referral to such entity, but shall make alternative arrangements for the referral.

D. Further, a practitioner may refer patients for health services to a publicly traded entity in which such practitioner has an investment interest, without applying for or receiving an exception from the Board, if all of the following conditions are met:

1. The entity's stock is listed for trading on the New York Stock Exchange or the American Stock Exchange or is a national market system security traded under an automated interdealer quotation system operated by the National Association of Securities Dealers;

2. The entity had, at the end of the corporation's most recent fiscal year, total net assets of at least \$50,000,000 related to the furnishing of health services;

3. The entity markets and furnishes its services to practitioner-investors and other practitioners on the same and equal terms;

4. All stock of the entity, including the stock of any predecessor privately held company, is one class without preferential treatment as to status or remuneration;

5. The entity does not issue loans or guarantee any loans for practitioners who are in a position to refer patients to such entity;

6. The income on the practitioner's investment is not tied to referral volumes and is based on the practitioner's equity interest in the entity; and

7. The practitioner's investment interest does not exceed one half of one percent of the entity's total equity.

E. In addition, a practitioner may refer a patient to such practitioner's immediate family member or such immediate family member's office or group practice for health services if all of the following conditions are met:

1. The health services to be received by the patient referred by the practitioner are within the scope of practice of the practitioner's immediate family member or the treating practitioner within such immediate family member's office or group practice;

2. The practitioner's immediate family member or the treating practitioner within such immediate family member's office or group practice is qualified and duly licensed to provide the health services to be received by the patient referred to the practitioner;

3. The primary purpose of any such referral is to obtain the appropriate professional health services for the patient being referred, which are to be rendered by the referring practitioner's immediate family member or by the treating practitioner within such immediate family member's

office or group practice who is qualified and licensed to provide such professional health services; and

4. The primary purpose of the referral shall not be for the provision of designated health services as defined in 42 U.S.C. § 1395nn and the regulations promulgated thereunder.

§ 54.1-2412. Board to administer; powers and duties of Board; penalties for violation.

A. In addition to its other powers and duties, the Board of Health Professions shall administer the provisions of this chapter.

B. The Board shall promulgate, pursuant to the Administrative Process Act (§ 2.2-4000 et seq.), regulations to:

1. Establish standards, procedures, and criteria which are reasonable and necessary for the effective administration of this chapter;

2. Establish standards, procedures, and criteria for determining compliance with, exceptions to, and violations of the provisions of § 54.1-2411;

3. Establish standards, procedures, and criteria for advising practitioners and entities of the applicability of this chapter to activities and investments;

4. Levy and collect fees for processing requests for exceptions from the prohibitions set forth in this chapter and for authorization to make referrals pursuant to subsection B of § 54.1-2411;

5. Establish standards, procedures, and criteria for review and referral to the appropriate health regulatory board of all reports of investigations of alleged violations of this chapter by practitioners and for investigations and determinations of violations of this chapter by entities;

6. Establish standards, procedures, and criteria for granting exceptions from the prohibitions set forth in this chapter; and

7. Establish such other regulations as may reasonably be needed to administer this chapter.

C. Upon a determination of a violation by the Board, pursuant to the Administrative Process Act, any entity, other than a practitioner, that presents or causes to be presented a bill or claim for services that the entity knows or has reason to know is prohibited by § 54.1-2411 shall be subject to a monetary penalty of no more than \$20,000 per referral, bill, or claim. The monetary penalty may be sued for and recovered in the name of the Commonwealth. All such monetary penalties shall be deposited in the Literary Fund.

D. Any violation of this chapter by a practitioner shall constitute grounds for disciplinary action as unprofessional conduct by the appropriate health regulatory board within the Department of Health Professions. Sanctions for violation of this chapter may include, but are not limited to, the monetary penalty authorized in § 54.1-2401.

§ 54.1-2413. *Additional conditions related to practitioner-investors.*

A. No hospital licensed in the Commonwealth shall discriminate against or otherwise penalize any practitioner for compliance with the provisions of this chapter.

B. No practitioner, other health care worker, or entity shall enter into any agreement, arrangement, or scheme intended to evade the provisions of this chapter by inducing patient referrals in a manner which would be prohibited by this chapter if the practitioner made the referrals directly.

C. No group practice shall be formed for the purpose of facilitating referrals that would otherwise be prohibited by this chapter.

D. Notwithstanding the provisions of this chapter, a practitioner may refer a patient who is a member of a health maintenance organization to an entity in which the practitioner is an investor if the referral is made pursuant to a contract with the health maintenance organization.

E. Notwithstanding the provisions of this chapter, a referral to an entity in which the referring practitioner or his immediate family member is an investor shall not be in violation of this chapter if (i) the health service to be provided is a designated health service as defined in 42 U.S.C. § 1395nn(h)(6), as amended, and an exception authorized by 42 U.S.C. § 1395nn, as amended, or any regulations adopted pursuant thereto, applies, or (ii) the health service to be provided is not a designated health service as defined in 42 U.S.C. § 1395nn(h)(6), as amended, but would qualify for an exception authorized by 42 U.S.C. § 1395nn, as amended, or any regulations adopted pursuant thereto, if the health service were a designated health service.

§ 54.1-2414. *Applicability of chapter; grace period for compliance.*

This chapter shall apply, in the case of any investment interest acquired after February 1, 1993, to referrals for health services made by a practitioner on or after July 1, 1993. However, in the case of any investment interest acquired prior to February 1, 1993, compliance with the provisions of this chapter is required by July 1, 1996.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board the authority to promulgate regulations:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

...

6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ [54.1-100](#) et seq.) and Chapter 25 (§ [54.1-2500](#) et seq.) of this title. ...

Alternatives

Please describe all viable alternatives for achieving the purpose of the existing regulation that have been considered as part of the periodic review process. Include an explanation of why such alternatives were rejected and why this regulation is the least burdensome alternative available for achieving the purpose of the regulation.

Chapter 24.1 provides the definitions and prohibited actions that would constitute practitioner self-referral in Virginia. To implement provisions of the Self-Referral Act, subsection B of § 54.1-2412 *mandates* that the Board of Health Profession promulgate regulations to:

- 1. Establish standards, procedures, and criteria which are reasonable and necessary for the effective administration of this chapter;*
- 2. Establish standards, procedures, and criteria for determining compliance with, exceptions to, and violations of the provisions of § 54.1-2411;*
- 3. Establish standards, procedures, and criteria for advising practitioners and entities of the applicability of this chapter to activities and investments;*
- 4. Levy and collect fees for processing requests for exceptions from the prohibitions set forth in this chapter and for authorization to make referrals pursuant to subsection B of § 54.1-2411;*
- 5. Establish standards, procedures, and criteria for review and referral to the appropriate health regulatory board of all reports of investigations of alleged violations of this chapter by practitioners and for investigations and determinations of violations of this chapter by entities;*
- 6. Establish standards, procedures, and criteria for granting exceptions from the prohibitions set forth in this chapter; and*
- 7. Establish such other regulations as may reasonably be needed to administer this chapter.*

In its 2012 review, staff of the Board of Health Professions found that no additional provisions to regulations are necessary for effective administration of the Practitioner Self-Referral Act. The regulation currently adopted is the least restrictive process format for implementation and has consistently provided a framework for requests for advisory opinions.

Public comment

Please summarize all comments received during the public comment period following the publication of the Notice of Periodic Review, and provide the agency response. Please indicate if an informal advisory group was formed for purposes of assisting in the periodic review.

The Notice of Periodic Review of the current regulation was published on November 21, 2011 with comment requested until January 20, 2012. There was no comment received.

Effectiveness

Please indicate whether the regulation meets the criteria set out in Executive Order 14 (2010), e.g., is necessary for the protection of public health, safety, and welfare, and is clearly written and easily understandable.

The regulations have been in effect since 1994; they were amended in 1999 and 2007. In order to clarify the provisions of law and update them in accordance with federal statutes, the Act was amended in 2000, 2005 and 2010. While no disciplinary actions have been initiated by the Board for failure to comply with the law, it has issued advisory opinions based on the process set forth in regulation. There has been one inquiry about an exception to the Act, but the health care entity did not meet the criteria for granting such a request. In compliance with subsection B of § 54.1-2412, it is essential that the Board continue the promulgation of regulations for Practitioner Self-Referral which protect public health and safety and provide for enforcement of the prohibitions of the Act.

Result

Please state that the agency is recommending that the regulation should stay in effect without change.

The Board of Health Professions is recommending that 18VAC75-20-10 et seq., Regulations Governing Practitioner Self-Referral, remain in effect without change.

Small business impact

In order to minimize the economic impact of regulations on small business, please include, pursuant to § 2.2-4007.1 E and F, a discussion of the agency's consideration of: (1) the continued need for the regulation; (2) the nature of complaints or comments received concerning the regulation from the public; (3) the complexity of the regulation; (4) the extent to which the regulation overlaps, duplicates, or conflicts with federal or state law or regulation; and (5) the length of time since the regulation has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulation. Also, include a discussion of the agency's determination whether the regulation should be amended or repealed, consistent with the stated objectives of applicable law, to minimize the economic impact of regulations on small businesses.

The prohibitions on practitioner self-referral are set forth in Chapter 24.1 of Title 54.1. Regulations in Chapter 20 provide a process by which an entity can receive an advisory opinion on whether a business arrangement would constitute a violation of the law. Regulations also provide a process by which a violation can be found and a disciplinary action imposed. No such

actions have been taken since passage of the law in 1993. Therefore, there is no economic impact of regulations on small businesses.

Family impact

Please provide an analysis of the regulation's impact on the institution of the family and family stability.

There is no impact on the institution of the family and family stability.